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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,514	09/22/2003	Marius Hauri	0100/0165	5820

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EXAMINER

HAYES, MICHAEL J

ART UNIT	PAPER NUMBER
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3767

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/665,514

Applicant(s)

HAURI ET AL.

Examiner

Michael J. Hayes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-24, 27 and 28 is/are rejected.
- 7) ☒ Claim(s) 6, 7, 25 and 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1 and 20 (and their dependent claims) are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no support in the specification as filed for a sheath attached only to the collar. The specification states at para. 31 that ribs 56 do not contact sheath, but there is no description that the hub does not contact the sheath. Though some figures may show non-contact between the hub and sheath this is not determinative of all embodiments or of only attaching the sheath to the collar.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 20-22 are rejected under 35 U.S.C. 102(b) as being anticipated by GYURE et al. (US Patent No. 5,681,295). Gyure best shows the sheath 337, hub 328 and collar 341 arrangement in fig. 12. Though Gyure states that the base is a separate piece assembled to the hub in an interference fit (like the interference fit of the collar to the hub) (col. 9, line 42 - col. 10, line 34), the prior art discloses that the base 330/30. The sheath has an engagement mechanism (proximal portion of the sheath fit into the collar in fig. 12) and the collar has an

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engagement portion (distal portion in contact with the sheath). In the same way that the collar is not considered a part of the hub, the base can also be considered not a part of the hub. In this view the sheath 337 is attached only to the collar because the base 330 and element 341 -are considered elements of the collar.

The method of making the assembly is inherent in the disclosure of the finished assembly of component parts.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over GYURE as applied claims 1 and 20 and further in view of LANDIS (US Patent No. 5,490,841). Gyure discloses the claimed invention except for the overlapping housing lips with off-centered opening. Landis teaches the use of overlapping housing lips with off-centered opening. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Landis in the apparatus and method of Gyure in order to easily entrap the needle with the housing.

Claims 9, 10, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over GYURE as applied to claims 1 and 20 above, and further in view of GYURE (US Patent No. 5,669,889). Gyure '295 discloses the claimed invention except for lock mechanisms on the

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collar and housing to matingly couple to retain the housing to the collar. Gyure '889 teaches lock mechanisms on the collar and housing to matingly couple to retain the housing to the collar (61, 57, fig. 3). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Gyure '889 in the apparatus and method of Gyure '295 in order to prevent the housing from re-exposing the needle after covering.

Claims 4 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over GYURE as applied to claims 1 and 20 above, and further in view of CRAWFORD. Gyure discloses the claimed invention except for a groove on the needle sheath to mate with a circumferential rib on the collar inner wall. Crawford teaches a groove and rib combination to secure a sheath to a collar. See fig. 2, 97 on collar and groove between elements 56 on sheath 50. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Crawford in the apparatus and invention of Gyure in order to provide a secure fit between the sheath and collar.

Claims 5 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over GYURE '295 as applied to claims 1 and 20 above, and further in view of Johnson (US Pub. No. 2002/0010433). Gyure '295 discloses the claimed invention as discussed above including a needle hub with luer end to connect to the luer end of the barrel (4:62-5:17). Gyure does not disclose a ring spaced around the hub end for a user to grasp. Johnson teaches a ring spaced around a hub end for a user to grasp (figs. 2a-e). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Johnson in the apparatus and method of Gyure in order to facilitate connection of the hub and barrel.

Claims 11, 12, 13, 16, 17, are rejected under 35 U.S.C. 103(a) as being unpatentable over JOHNSON et al. US Pub. No. 2002/0010433 in view of GYURE '295 and LOCKHART (US Patent No. 2,693,183). Johnson discloses a needle hub having a luer connection 68 at a proximal portion, and a ring 42 surrounding, in spaced relation, to the luer connector (figs. 2A-2F). Johnson does not disclose a window provided at the hub ring, a collar having a pivotally connected housing rotatable about the hub, first and second engagement mechanisms. Gyure best shows the sheath 337, hub 328 and collar 341 arrangement in fig. 12. Though Gyure states that the base is a separate piece assembled to the hub in an interference fit (like the interference fit of the collar to the hub) (col. 9, line 42 - col. 10, line 34), the prior art discloses that the base 330/30. The sheath has an engagement mechanism (proximal portion of the sheath fit into the collar in fig. 12) and the collar has an engagement portion (distal portion in contact with the sheath). In the same way that the collar is not considered a part of the hub, the base can also be considered not a part of the hub. In one view the sheath 337 is attached only to the collar because the base 330 and element 341 -are considered elements of the collar. Gyure further teaches a collar having a pivotally connected housing rotatable about the hub (Fig. 12) to position a needle guard adjacent a needle that can cover the needle to protect against accidental punctures.

Furthermore, claim 11 does not require the limitation of attaching a sheath only to a collar. In this regard Gyure '295 discloses a safety apparatus including a needle hub, collar rotatably mounted, housing pivotally connected to the collar, needle sheath 37, engage mechanisms (40 and proximal portion, hub distal portion) on the sheath and collar respectively,

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needle hub with flange and wall 33, 32, and collar protrusion 43 as recited in claim 17. See fig. 2.

It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Gyure '295 in the safety apparatus of Johnson in order to lower the risk of accidental punctures with syringe needles by shielding the needle. Lockhart teaches a window at a needle hub to allow visual access to the interior of the hub. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Lockhart in the safety apparatus of Johnson and Gyure '295 in order to see if blood was present on the interior surface of the hub that could contaminate surfaces during or after use of the needle hub.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over JOHNSON, GYURE '295, and LOCKHART as applied to claim 12 above, and further in view of CRAWFORD (US Pub. No. 20020161336). Johnson, Gyure '295, and Lockhart disclose the claimed invention except for a groove on the needle sheath to mate with a circumferential rib on the collar inner wall. Crawford teaches a groove and rib combination to secure a sheath to a collar. See fig. 2, 97 on collar and groove between elements 56 on sheath 50. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Crawford in the apparatus and invention of Johnson, Gyure '295, and Lockhart in order to provide a secure fit between the sheath and collar.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over JOHNSON, GYURE '295, and LOCKHART as applied to claim 11 above and further in view of LANDIS. Johnson, Gyure '295, and Lockhart disclose the claimed invention except for the overlapping housing lips with off-centered opening. Landis teaches the use of overlapping housing lips with

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off-centered opening. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Landis in the apparatus and method of Johnson, Gyure '295, and Lockhart in order to easily entrap the needle with the housing.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over JOHNSON, GYURE '295, and LOCKHART as applied to claim 11 above, and further in view of GYURE (US Patent No. 5,669,889). Johnson, Gyure '295, and Lockhart disclose the claimed invention except for lock mechanisms on the collar and housing to matingly couple to retain the housing to the collar. Gyure '889 teaches lock mechanisms on the collar and housing to matingly couple to retain the housing to the collar (61, 57, fig. 3). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Gyure '889 in the apparatus and method of Johnson, Gyure '295, and Lockhart in order to prevent the housing from re-exposing the needle after covering.

Allowable Subject Matter

Claims 6, 7, 25, and 26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, and upon overcoming the 112(1) rejection described above.

Response to Arguments

Applicant's arguments with respect to claims 1-28 have been considered but are moot in view of the new ground(s) of rejection.

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Conclusion


Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (571) 272-4959. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. The fax number for submitting official papers is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh
17 April 2006


MICHAEL J. HAYES
PRIMARY EXAMINER